

### **REMARKS/ARGUMENTS**

In response to the Final Office Action mailed September 14, 2005, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claims 1 and 20 are proposed to be amended, no claims have been added, and no claims have been cancelled so that Claims 1-40 are currently pending. No new matter has been introduced.

Claims 1-10, 20, 21 and 28-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,472,702 to Muth et al (Muth) in view of U.S. Patent No. 5,749,203 to McGowan, Jr. (McGowan). This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under

35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Both Muth and McGowan are directed to methods of sterilization. In Muth a device and a protein are being sterilized whereas in McGowan a device is sterilized. However, neither of the references, whether taken alone or in combination, discloses or even remotely suggests sterilizing a medical device coated with a rapamycin as is claimed in the present invention. This is a specific drug class and not set forth in the cited art. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 22-27 were rejected as being unpatentable over Muth in view of McGowan and further in view of U.S. Patent No. 5,464,580; Claims 11-13 and 32-34 were rejected as being unpatentable over Muth in view of McGowan and further in view of U.S. Patent No. 6,025,414 to Rich and U.S. Patent No. 3,675,647 to Pharriss et al.; and Claims 14-19 and 35-40 were rejected as being unpatentable over Muth in view of McGowan and further in view of WO 00/38754 to Gingras. These rejections are respectfully traversed.

None of the references, whether taken alone or in combination, fail to disclose all of the claimed features. Specifically, these references fail to disclose or suggest what is missing from Muth and McGowan, namely, sterilizing a device with a rapamycin coating. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

The Reply raises no new issues and places the application in form for allowance therefore; entry is proper and earnestly solicited.

Respectfully submitted,

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Dated: November 10, 2005